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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,415	06/26/2006	Yasuomi Urano	062522	9423

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EXAMINER
ROYDS, LESLIE A

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,415	URANO ET AL.	
	Examiner	Art Unit	
	LESLIE A. ROYDS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-9 and 15-23* is/are pending in the application.

4a) Of the above claim(s) *15-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *28 April 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 5-9 and 15-23 are presented for examination.

Applicant's Amendment and Information Disclosure Statement (IDS) filed April 28, 2009 have each been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08a (two pages total), the Examiner has considered the cited references.

Claims 5-9 and 15-23 remain pending. Claims 5-9 are under examination and claims 15-23 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 5-9 are amended. Claims 1-4 and 10-14 are cancelled.

Applicant's arguments, filed April 28, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 5 is directed to a method of treating a disorder associated with the activation of γ-secretase by inhibiting the formation of an active complex of γ-secretase comprising the step of

administering an effective amount of a cholesterol synthesis inhibitor or a protein geranylgeranylation regulator to a patient in need of inhibiting the γ-secretase activity in a nerve cell.

In particular, the specification as originally filed fails to provide adequate written description for the genus of disorders associated with the activation of γ-secretase (claim 5).

MPEP §2163 states, "The issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not convention in the art or known to one of ordinary skill in the art…The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))…Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was

in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Applicant states at p.14 of the instant specification, "In addition, the present invention provides a method of treating or preventing disorder associated with the activation of γ-secretase by administration of an effective amount of the cholesterol synthesis inhibitor or the protein geranylgeranylation regulator of the present invention to a patient in need of inhibiting the γ-secretase activity. As for the patient with a disease in need of inhibition of the γ-secretase activity, the production of Aβ40, Aβ42 peptide, particularly the production of Aβ42 by the formation of an active complex of γ-secretase has to be inhibited, and such disease caused by the deposition of these peptides includes, for example, Alzheimer's disease (AD)."

While the exemplary disorder associated with the activation of γ-secretase of Alzheimer's disease has been duly noted, it remains that Applicant has failed to provide any limiting definition of the genus of disorders associated with activation of γ-secretase that Applicant was in possession of, and intended to be treated using the presently claimed genus of compounds, at the time of the invention, aside from the single disorder of Alzheimer's disease. In other words, Applicant has failed to provide any description of the specific disorders (aside from the exemplary disorder of Alzheimer's disease) that would fall within the claimed genus such that other members of the claimed genus could be immediately envisaged and/or readily identified. The idea that, in order to identify the other members of the genus, one of skill in the art would have to undertake extensive hit or miss testing to determine the full scope of the genus is clearly indicative of the fact that Applicant was, in fact, *not* in possession of the full scope of disorders associated with the activation of γ-secretase. This is because Applicant cannot logically be in possession of that which he has yet to identify. MPEP §2163 states, "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the

invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention." Absent such description of distinguishing identifying characteristics to demonstrate that Applicant had contemplated, and, thus, had possession of, other disorders aside from Alzheimer's disease, the instant specification lacks adequate written description of the claimed genus. Furthermore, Applicant fails to point to any disclosure in the art to establish that the state of the art was well-developed with regard to disorders associated with the activation of γ-secretase such that the other disorders falling within the claimed genus would have been readily apparent to one of ordinary skill in the art at the time of the invention.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the full scope of disorders associated with activation of γ-secretase (claim 5).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cai et al. (WO 03/077896; September 2003).

Cai et al. teaches a method for treating or slowing the progression of Alzheimer's disease comprising administering an effective amount of an HMG-CoA reductase inhibitor in combination with a therapeutically effective amount of an ACAT inhibitor to a patient in need thereof (p.3, l.9-12), wherein the HMG-CoA reductase inhibitor is selected from, *inter alia*, pitavastatin (p.4, l.11-17, particularly l.15). Note that the teaching of the treatment of Alzheimer's disease in a patient in need thereof meets Applicant's instantly claimed limitations directed to the treatment of "a disorder associated with the activation of γ-secretase" and "a patient in need of inhibiting the γ-secretase activity in a nerve cell" as recited in, e.g., instant claim 5, because Applicant defines the disorder and the patient suffering therefrom at p.14, l.8-17 of the instant specification as, e.g., Alzheimer's disease.

Regarding Applicant's objective of inhibiting the formation of an active complex of γ-secretase (claim 5) or the inhibition of the formation of an active complex of γ-secretase in lipid rafts (claim 6), the pitavastatin compound disclosed by Cai et al. is identical to the compound presently recited (and elected) in Applicant's instant claims and is used in the same manner (i.e., administered in the same manner to the same subject for the treatment of the same disorder as prescribed in the instant claims) as that instantly claimed. Therefore, the method of use disclosed by Cai et al. must necessarily possess the same function inhibiting the formation of an active complex of γ-secretase (as in instant claim 5) or inhibiting the formation of an active complex of γ-secretase in lipid rafts (as in instant claim 6) as that instantly claimed whether recognized by the patentee or not because products of identical chemical composition cannot have mutually exclusive properties when used in exactly the same manner. In other words, if the prior art teaches the identical chemical and/or physical structure of the claimed compound and further teaches the identical manner of using the same, the properties that Applicant discloses and/or claims are necessarily present. Please see MPEP §2112.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.,* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.,* 335 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Conclusion

Rejection of claims 5-9 is proper.

Claims 15-23 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the

advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE A. ROYDS whose telephone number is (571)272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

July 21, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614